Complete Summary

GUIDELINE TITLE

Guidelines for the surgical practice of telemedicine.

BIBLIOGRAPHIC SOURCE(S)

Guidelines for the surgical practice of telemedicine. Los Angeles (CA): Society of American Gastrointestinal Endoscopic Surgeons (SAGES); 2004 Mar. 12 p. [25 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

METHODOLOGY - including Rating Scheme and Cost Analysis
RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
QUALIFYING STATEMENTS
IMPLEMENTATION OF THE GUIDELINE
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT
CATEGORIES

IDENTIFYING INFORMATION AND AVAILABILITY

DISCLAIMER

SCOPE

DISEASE/CONDITION(S)

Diseases/conditions requiring surgical intervention

GUIDELINE CATEGORY

Diagnosis Evaluation Management Treatment

CLINICAL SPECIALTY

Surgery

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To develop a framework for understanding and categorizing basic telemedicine concepts and activities, and to establish guidelines for the safe surgical practice of telemedicine

TARGET POPULATION

Persons undergoing surgery

INTERVENTIONS AND PRACTICES CONSIDERED

- 1. Telemedicine
- 2. Teleconferencing
- 3. Teleproctoring
- 4. Telemonitoring
- 5. Teleconsulting
- 6. Telemanagement
- 7. Telesurgery

MAJOR OUTCOMES CONSIDERED

Not stated

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

This statement was reviewed and approved by the Board of Governors of the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES), March 2004.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Telemedicine

Definition:

The practice of medicine and/or teaching of the medical art, without direct physical physician-patient or physician-student interaction, via an interactive audio-video communication system employing tele-electronic devices.

Appropriate Use:

Some applications of consultation, diagnosis and teaching with the potential for treatment as defined below.

Remote Site (Site of the Primary Activity)

Definition:

The site or location of the primary activity. This location may be the originating site of a conference, the laboratory where a new technique, instrument, or technology is being demonstrated, the facility where a patient is being evaluated or treated, or the operating theater where a surgical procedure is being performed.

Central Location (Central Site)

Definition:

The site of the teacher, demonstrator, evaluator, student, or clinician which is not immediately adjacent or proximate to the primary site of the activity or procedure. The central or offsite location may be as little as 100 feet or as distant as several thousand miles from the primary site of a conference or patient interaction. The basic assumption here is that the individual at the central site is not able to physically intervene immediately in the primary procedure without the telecommunications interface.

Comments:

The concept of interaction at a distance implies that some form of telecommunications medium is employed. The participants, facilities, and telecommunication service vendors involved in the event should coordinate their efforts so that the telecommunications interface is suitable for the planned activity.

Teleconferencing

Definition:

A real time and live interactive program in which one set of participants are at one or more locations and the other set of participants are at another location. The teleconference allows for interaction, including audio and/or video, and possibly other modalities, between at least two sites.

Appropriate Use:

Teaching (e.g., didactic lectures, demonstration of surgical or other medical procedures, and demonstration of uses of equipment), consultation, diagnosis, or deliberations. (See: Teleconsulting below)

Comments:

Teleconferencing may be a useful adjunct to hands-on experience in the instruction of new procedures but is not a substitute for on-site supervised hands-on training in the development of competency.

Teleproctor

Definition:

An expert surgeon, at a central site, who undertakes to impart his/her clinical knowledge and skills in a defined setting to a student. The teleproctor must be appropriately privileged, skilled, and experienced in the procedure(s) and/or technique(s) in question. In order to serve as a teleproctor in a specific procedure or technique, the surgeon (teleproctor) must be a recognized authority (e.g., publications, presentations, extensive clinical experience) in the particular field of expertise. The teleproctor, by definition, does not have the ability to physically intervene on-site in the primary activity without the telecommunications interface.

Teleproctoring

Definition:

A real time and live interactive teaching of techniques or procedures by a teleproctor to a student. The teleproctor is in one location and the student is in another. The teleproctor must have the ability to see the performance of the procedure or technique being executed by the student in real time. The teleproctor and the student must have the ability to verbally communicate during the session. Implicit in the definition of teleproctoring is that the teleproctor does not have the ability to physically intervene on-site and can therefore not assume primary patient care responsibility.

Appropriate Use:

- Demonstration and/or teaching technique or procedures using inanimate trainers.
- Demonstration and/or teaching techniques or procedures using animate ex vivo models.
- Demonstration and teaching techniques or procedures on patients as an adjunct teacher when a qualified preceptor is on-site with the student.

Comments:

Teleproctoring is not an acceptable substitute for an on-site preceptorship but may be a useful adjunct.

Telemonitor/Teleproctor

Definition:

A person who supervises or monitors students from a central location. As defined here, a teleproctor differs from a consultant or a preceptor in that (s)he functions as an observer and evaluator, does not directly participate in patient care, and

receives no fees from the patient. The teleproctor acts as an agent of the privileging committee of the sponsoring hospital. The teleproctor, by definition, does not have the ability to physically intervene on-site without the telecommunications interface and therefore cannot assume primary patient care responsibility.

A teleproctor must be a physician/surgeon who has recognized proficiency or documented expertise in the specialty area being monitored. The teleproctor should be free of perceived or actual conflicts of interest, which might create a bias against, or in favor of, the applicant. A teleproctor may work at the same or at another institution.

Teleproctoring

Definition:

A real time and live interactive monitoring (evaluation) of technique(s) or procedure(s) of an applicant seeking privileges, or a surgeon seeking to certify or document his competence in a specific technique or procedure(s). The teleproctor is in one location and the surgeon to be evaluated is in another. The teleproctor must have the ability to see the performance of the procedure or technique being executed by the student in real time. The teleproctor and the applicant must have the ability to verbally communicate during the session.

Appropriate Use:

Teleproctoring may be used as an adjunct to proctoring in the privileging process but should not alone be a substitute for proctoring to determine competency. Integration of teleproctoring into the proctoring process may reduce, but not eliminate, the number of on-site proctored cases required.

Comments:

The term-teleproctoring is sometimes used to define remote patient surveillance. For the purposes of this document, teleproctoring is not used in that context, but rather as described above. Remote patient surveillance is an activity that is included in the concept of telemanagement.

Teleproctoring assumes that the ability of the teleproctor to physically intervene at the site of the primary procedure is not possible without the telecommunications interface.

Teleconsultant

Definition:

A physician at a central location who evaluates a patient, and/or patient data, and who presents an opinion of his or her findings and/or recommendations for further evaluation or treatment to the patient or other health care provider at the remote site, using a telecommunications interface.

Teleconsulting (Remote Patient Evaluation & Consultation)

Definition:

Evaluation of patient(s), and/or patient data, and consultation regarding patient management, from a distant site, using a telecommunications interface. The teleconsultant, by definition, does not have the ability to physically interact with the patient, except through the telecommunications interface.

Appropriate Use:

- Initial urgent evaluation of patients, triage decisions, and pretransfer arrangements for patients in an urgent/emergency situation
- Intra-operative consultations
- Supervision and consultation for primary care encounters in sites where an equivalently qualified physician/surgeon is not available
- Routine consultations and second opinions based on history, physical findings, and available test data
- Public health, preventive medicine, and patient education

Comments:

Teleconsulting has heretofore represented the pinnacle of achievement in telemedicine applications. Its use in the fields of radiology and pathology has stimulated the development of specific guidelines regarding the minimum and suggested interface requirements for reliable interpretation of transmitted patient information. In other disciplines, minimum requirements for the telecommunications interface remain to be defined. However, teleconsulting with telesurgical presence should include high speed, uninterrupted transmission, similarity of operating room environments with necessary instruments previously agreed upon and an absence of language barriers between the consultant and the operating team. Utilizing these criteria expert telesurgical consultation has been provided for even complex surgical problems.

Remote patient evaluation assumes that a remote health care provider, who is familiar with, and capable of using the telecommunications interface equipment, is present with the patient or that the patient has been instructed in the mechanics of, and is capable of applying the diagnostic and telecommunications instrumentation necessary to provide clinical information to the teleconsultant.

Telemanagement (Remote Patient Management)

Definition:

Remote evaluation and non-operative treatment of a patient, using a telecommunications interface.

Appropriate Use:

Medical and surgical evaluation, follow-up, and medication checks

- Management of chronic diseases and conditions requiring a specialist not available locally
- Public health, preventive medicine, and patient education

Comments:

Telemanagement of a patient assumes that the central physician has evaluated the patient, and/or patient data, concurrently with the management activity.

Because it involves a level of physician-patient interaction comparable to, or more intense than teleconsulting, telemanagement requires that a remote health care provider, who is familiar with, and capable of using the telecommunications interface equipment, is present with the patient, or that the patient has been instructed in the mechanics of, and is capable of applying the diagnostic and telecommunications instrumentation necessary to provide clinical information to the central site physician.

Telesurgery (Remote Surgery)

Definition:

Surgery, procedure or intervention performed on an inanimate trainer, animate model, or patient, in which the surgeon or operator is not at the immediate site of the model or patient being operated upon. Visualization and manipulation of the tissues and equipment is performed using tele-electronic devices.

Appropriate Use:

- Demonstration and/or teaching technique or procedures using inanimate trainers as the objects of the procedure.
- Demonstration and/or teaching techniques or procedures using animate model for purposes of testing technology.
- Demonstration and teaching techniques or procedures on patients under strict guidance of an Institutional Review Board (IRB) and only when a qualified surgeon is present to intervene in a timely fashion if technical difficulties arise.

Comments:

Remote surgery remains investigational and should be performed with IRB approval and only by surgeons familiar with the technology. The introduction of telerobotic surgery, coupled with improvements in bandwidth and reduction in time has allowed for the remote safe completion of common surgical procedures.

The Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) strongly urges surgeons to conduct the clinical use of telesurgery and telerobotics under IRB auspices. Quality assurance and outcomes data should be routinely collected. Surgeons utilizing telerobotics should undergo appropriate training and be aware of the anesthetic implications of this technology. All involved participants, facilities, telecommunication and equipment vendors should coordinate their efforts to provide secure visual fidelity and smooth

telecommunications interfaces. The development of global standards should be actively pursued.

Since 4/14/03 (Health Insurance Portability And Accountability Act compliance date), protected health information (PHI), needs to be managed in accordance with Federal regulations. Simple de-identification such as removal of the patient's name or avoidance of facial photography, which was sufficient in the past does not meet all of the requirements today. "Live surgery" by its very nature adds identifiers in two categories that need to be considered under the law. They are "dates of service" which is the day of the transmission and geographic location (less than 20,000 persons) of the procedure (i.e., the hospital). Since these are unavoidable, an authorization from the patient must be obtained. This is the patient's physician responsibility prior to disclosing PHI outside of the covered entity where the procedure is taking place.

This authorization should indicate:

- 1. It is very unlikely that the patient could be identified individually (unless the patient authorizes the disclosure of his or her name or allows the use of facial photography)
- 2. The nature of the PHI to be disclosed (in most cases this is date of surgery and location of care)
- 3. The nature of those persons who will be in receipt of PHI and the fact that federal law does not require those same persons to keep the PHI confidential
- 4. The expiration date of the authorization

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting the recommendation is not specifically stated.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate policies and procedures to promote safe, high quality application of telemedicine technology to the practice of surgery

POTENTIAL HARMS

Not stated

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- Society of American Gastrointestinal Endoscopic Surgeons (SAGES) strongly urges surgeons and hospitals to defer clinical implementation of these modalities until the technology has been validated. It is the developer's opinion that current clinical use of this technology should only be conducted under a protocol reviewed by an institutional committee for the protection of patients and should include the collection of quality assurance and outcomes data. The participants, facilities, and telecommunication service vendors involved in these events should coordinate their efforts so that the visual fidelity and telecommunications interface is suitable for the planned activity.
- Remote surgery remains investigational and should be performed with institutional review board approval and only by surgeons familiar with the technology. The introduction of telerobotic surgery, coupled with improvements in bandwidth and reduction in time has allowed for the remote safe completion of common surgical procedures.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better Living with Illness

IOM DOMAIN

Effectiveness Patient-centeredness Safety

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2004 Mar

GUIDELINE DEVELOPER(S)

Society of American Gastrointestinal and Endoscopic Surgeons - Medical Specialty Society

SOURCE(S) OF FUNDING

Society of American Gastrointestinal and Endoscopic Surgeons (SAGES)

GUIDELINE COMMITTEE

Guidelines Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

SAGES members are assigned by leadership to the Guidelines Committee

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available from the <u>Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) Web site</u>.

Print copies: Available from the Society of American Gastrointestinal Endoscopic Surgeons (SAGES), 11300 W. Olympic Blvd., Suite 600, Los Angeles, CA 90064; Web site: www.sages.org.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI Institute on May 2, 2007. The information was verified by the guideline developer on May 13, 2007.

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